REMARKS

I. Status of the Claims

Claims 1-3, 5-8 are amended.

Claims 1-8 are pending.

II. Claims Are Enabled for Osteogenesis Induced in Cranial Sutures by Cyclic Forces

A. Citations to the Specification show claims 1-8 are Enabled

Claims 1-8 were rejected under 35 U.S.C. §112, first paragraph. The examiner admits that:

> The specification describes the device for realigning teeth, how to use the device, and method of realigning teeth . . . .

Action, page 2, paragraph 2

but believes the only support in the application for claims 1-8 to bone remodeling and modeling is on page 16.

However, there is clear proof in the application of the effects of cyclic forces on osteogenesis and bone remodeling including how to achieve such claimed effects. The invention is clearly stated in page 5, 6 and 9 as use of cyclic forces which, as discussed in the Background, page 3, had not been applied to facial remodeling by others.

> Cyclic forces are shown here to stimulate more effective sutural osteogenesis than static forces.

On page 9, lines 16-18

Cyclic forces "rapidly change magnitude over short time, e.g. several cycles per second."

This is the thrust of the claimed invention. The examiner has **not** shown this method is not enabled. To the contrary, the examiner has failed to consider the express enablement in the specification.

Further support in the specification for claims 1-8 relating induction of craniofacial suture osteogenesis, not malocclusion, may be found in the specification at least in the following locations:

page	lines	comment
5	first full paragraph	"Contemporary orthodontists not only use braces to align the teeth, they also use **orthopedic appliances such as headgear and facemask to change the shape of facial bones so that the overall facial shape is esthetically pleasant**. The present technology (described hereinafter), in addition to providing a mechanism for rapidly aligning the teeth, also provides pathways by which the **shape of facial bones can be rapidly changed**, although the precise characteristics of the forces responsible for the two approaches are different. The present invention that is described hereinafter provides for the **remodeling of craniofacial bones** and treatment of malocclusion through the **use of cyclic force application to the region to be remodeled**." (*emphasis provided*)
6	2-3, 9-17	"cyclic forces are used to expedite the remodeling of craniofacial bones to correct dentofacial deformities . . . ." "applying cyclic forces to a craniofacial suture region of the mammal in which osteogenesis is desired with a peak magnitude about 10 Newtons or 0.1 to about 5 . . . ." frequency up to about 40 Hz, or 0.1 to about 8 Hz. - repeatedly.

7	Par. 1	describes apparatus to deliver "cyclic force"
8	Par. 2 Fig. 1	"craniofacial bone restructering" demonstrates "increase in anterior facial length (AFL) of treated rabbits using a cyclic force application process of the present invention . . ."
10 11	3 - 15, 29 entire page	extensive enablement of sutural osteogenesis by applying a cyclic force "particularly useful for inducing osteogenesis in craniofacial sutures."
12	entire page	defines "cyclic force."
12 13	15-33 1-3	predetermined time period enabled
14	Fig. 3	enables delivery of a cyclical force
15	30	Micro Mo Electronics, Inc.
16	31-33	devise for reshaping cranial bone
17- 22	entire pages	results of rabbit study, enablement of cyclic forces delivered to maxilla producing facial growth, cranial growth, sutural separation and proliferation of osteoblast - like cells.
	Fig. 1	graphs demonstrating effects on cranial bones

Undue experimentation is not required to select parameters to practice the invention as claimed. For example, on pages 17-22 of the specification, there is demonstration of successful use of cyclic forces to improve facial lengths by practice of the invention - application of cyclic forces.

Extensive description of placement of strain would inform one of skill in the art where forces are applied to produce strain. This demonstrated "strain-induced osteogenesis" (p. 21). Those of skill in the art, taught by the specification, would know how to apply cyclic forces to cranial sutures. Orthodontists already use orthopedic appliances such as headgear and face masks to change the shape of facial bones (specification p. 5, 1st full paragraph, see also Exhibit A). They can readily engineer devices to incorporate cyclic instead of static forces tailored for desired bone remodeling.

B. A Declaration Under 37 C.F.R. § 1.132 States The Specification is Enabling

During the Interview of August 17, 2005, it was suggested that a "supplemental statement" would be helpful to show those of skill in the art could practice the invention. A Declaration under C.F.R. § 1.132 from a Craniofacial Biology expert, Dr. Adriana Da Silveira, testifying that the specification is enabling is enclosed as Exhibit A.

C. The Provisional Application Supports Osteogenesis of Craniofacial Sutures

During the Interview of August 17, 2005, the examiner wondered what enablement was in the provisional application, U.S. Ser. No. 60/2343,530, claimed as priority for the parent application.

A review of the provisional application shows:

Page 2

> to "determine whether cyclic forces can induce more effective sutural osteogenesis than static forces . . . cyclic forces were delivered to the rabbit maxilla in ventral direction."
>
> "data demonstrate, for the first time, that 1) *in vivo* bone strain over the premaxilliomaxillary and nasofrontal sutures in the rabbit is a frequency-modulated event . . . can induce sutural osteogenesis in the premaxilliomaxillary suture."

Page 4

> "clinical practicioners . . . . have fabricated numerous mechanical devices to augment or retard sutural osteogenesis in order to modify the natural shape of craniofacial skeleton."

Page 11

> "The functional significance . . . 2) capability of cyclic forces to modulate sutural osteogenesis in a model towards therapeutic use of cyclic forces in patents with craniofacial anomalies, dentofacial deformities, and malocclusion."

Page 17

FIG. shows the relation between direction of applied mechanical stimuli and cranial sutures in the rabbit.

Please withdraw the rejections under 35 USC § 112 and pass claims to allowance.

III. Other Issues

Claims 1, 5 and 7 are amended to correct antecedents and to make all spellings "cyclic" (not "cyclical") - both are correct and are used in the specification..

In the Interview of August 17, 2005, the examiner requested "new matter" submitted by applicant's previous representative, be removed. Without agreeing that the "incorporation by reference" in the previous response is "new matter," as the examiner believes, applicant's new representative will not depend on that incorporation, therefore, please remove it. Reference was to the provisional application which was included on the Application Data sheet on issued patent 6,648,639.

Please contact applicants' representative if you have any questions.

No other fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21726/99563).

Respectfully submitted,

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